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Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Network and Central '02

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

July 27, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Network and Central '02

COMMON NAME:

Clinical network and central station

CLASSIFICATION NAME:

The following Class II classification appears applicable:

System, network and communication, physiological monitors 870.2300

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5 Network and Central '02 is substantially equivalent in safety and effectiveness to the Datex-Ohmeda S/5 Network and Central '01 (510(k) number: K013246).

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DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5 Network '02 (also referred as D-O Network in the related documentation) is a system, which consists of networked devices (which have separate 510(k) clearance) and the actual networking hardware. The networked devices are Datex-Ohmeda products containing a network adapter for physical access to the D-O Network as well as software modules supporting network access. Examples of currently available networked devices are:

1. Datex-Ohmeda S/5 Anesthesia Monitor
2. Datex-Ohmeda S/5 Compact Anesthesia Monitor
3. Datex-Ohmeda S/5 Critical Care Monitor
4. Datex-Ohmeda S/5 Compact Critical Care Monitor
5. Datex-Ohmeda S/5 Light Monitor
6. Datex-Ohmeda S/5 Cardiacap 5 Monitor
7. Datex-Ohmeda S/5 Network and Central '02, included in this 510(k)
8. Datex-Ohmeda S/5 Telemetry System

The DeioRecorder for Anesthesia (formerly named as Datex-Ohmeda AS/3 Record Keeper) is also related to the D-O Network as an application using the services provided by the D-O Network. The Datex-Ohmeda S/5 Central (also referred to as D-O Central in the related documentation) is the primary maintainer of communication between other networked devices and is, thus, an essential part of the network. The structure and functionality of the revised network corresponds to the structure and functionality of the substantially equivalent predicate device Datex-Ohmeda Network and Central '01 (510(k) number: K013246). The Datex-Ohmeda Network will be used for real-time communication between devices, for record keeping and for data management in a hospital. Practical examples of currently available features are:

- Transmission and display of measured values and alarms in the Datex-Ohmeda S/5 Central screen (central monitoring) and on the screen of another networked monitor (monitor-to-monitor communication).
- Anesthesia record keeping.
- Storing and transferring of trend and record keeping data in the network. When the patient is moved from one monitor to another, the data can be transferred with the patient. This feature includes also transferring data from/to an external system (HIS, laboratory, etc.) to/from Datex-Ohmeda S/5 Network.
- Printing of anesthesia records, ICU reports, trend printouts, spirometry loop printouts, waveform snapshot printouts, etc.

The actual networking hardware consists of cabling, patch panels, racks, connectors, repeaters, access points with antennas etc. The networking hardware is similar to the networking hardware of the substantially equivalent predicate device Datex-Ohmeda Network and Central '01 (510(k) number: K013246) with additional wireless LAN hardware. The Datex-Ohmeda S/5 ViewStation is a D-O Central version that can show real-time curves and numeric information from any monitor residing in the Datex-Ohmeda Network. It also allows printing to laser printer or recording to a strip-chart recorder. The Datex-Ohmeda S/5 ViewStation does not store patient data, or provide any other network services than display and printing services. The ViewStation uses the same hardware and a subset of the software used by the main Central.

The Datex-Ohmeda S/5 Telemetry System Network (also referred as S/5 TeleCentral is a computer-based system for monitoring patients using telemetry. It consists of a PC based Central Station including receivers, antenna network, and up to 16 telemetry transmitters per station. The central station supports arrhythmia monitoring, and measuring and trending of ST changes. An S/5 TeleNet Package enables connection of Telemetry central to D-O Network. The package enables transfer of ECG waveforms, ECG related parameters and arrhythmia information to the D-O Network. Also bed-to-bed services from telemetry sessions to bedside monitors are made available.

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Modifications to the predicate device Datex-Ohmeda Network and Central '01, K013246 are as follows:

Wireless LAN hardware: The Datex-Ohmeda Network as an option can use commercial WLAN technology products as the access points with antennas and power supply units to replace the cable in the communication path.

PC hardware: A new version of the PC for the Central and Viewstation has been specified because manufacturing of the earlier one was discontinued. The requirements for the PC have remained the same.

The new version of Datex-Ohmeda S/5 Network and Central SW adds the following features:

- A symbol for a monitor with wireless LAN connection has been added to the user interface.
- Extension of network size to consist of up to 32 Centrals and 32 Viewstations instead of the earlier 4 Centrals and 4 Viewstations
- Trend data continuum is extended to work within eight Centrals instead of the earlier four.

INTENDED USE as required by 807.92(a)(5)

Intended use:

The Datex-Ohmeda S/5 Network and Central is intended to be used with Datex-Ohmeda devices for displaying, storing, printing and otherwise processing information received from other networked devices.

Indications for use:

The Datex-Ohmeda S/5TM Network and Central transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several Centrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.

The Datex-Ohmeda S/5TM Central maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in Datex-Ohmeda monitor network. Network connections consist of hardwired network cables and/or Wireless LAN (WLAN) connections. Furthermore, it coordinates the transfer of information between devices in the Datex-Ohmeda S/5TM Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS). The Datex-Ohmeda S/5TM Central can be used for remote monitor management, storing, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5TM ViewStation can be used for remote monitor management, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5TM Network will be used for patients in the hospital and it is meant for continuous use. The device is for use by qualified personnel only.

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SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE
PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5 Network and Central '02 is substantially equivalent in safety and effectiveness to the Datex-Ohmeda S/5 Network and Central '01 (510(k) number: K013246) currently in distribution.

Similarities:

The indications for use are the same as in the predicate except that "Network connections consist of hardwired network cables and/or Wireless LAN (WLAN) connections." has been expressed in the statement. The structure and functionality of the Datex-Ohmeda S/5 Network and Central '02 closely corresponds to the structure and functionality of the Datex-Ohmeda Network and Central '01 (predicate). The basic architecture of Datex-Ohmeda S/5 Network and Central '02 is the same as that of Datex-Ohmeda Network and Central '01 (predicate). The user interface is the same as the predicate. Only a symbol for a wireless connection to a monitor has been added. uses the same basic functionality: Single patient view and multiple patient views are the same as in the predicate. All alarm functionality in the new Central and the predicate are identical.

Differences:

The Datex-Ohmeda Network can now use the commercial WLAN technology products as the access points with antennas and power supply units to replace the cable in the communication path. Any combination of wired and wireless connection can be used. The wireless communication doesn't effect the functionality of the Datex-Ohmeda S/5 Network and Central. The network size is extended from four Centrals and four Viewstations to accommodate up to 32 Centrals and 32 Viewstations. Each Central can be connected to a maximum three other Centrals and maximum four Viewstations for viewing of patient data. Each Viewstation can be connected to a max. four Centrals. The connections are selected individually for each Central. The extension doesn't affect the load level of an individual Central, since the number of connections to any given Central remains the same. Trend data continuum (=patient data continuum) is extended to work within eight Centrals instead of the earlier four. On each Central there is a possibility to define seven other Centrals from which patient data loading is possible. It is an extension of the predicate functionality and does not affect the load level of Centrals. On monitor this enables trend data, that is stored on the Central, to be loaded from seven other Centrals. This enables loading of data from other care areas, where the patient may earlier have been monitored. The symbol for wireless connection has been added to the user interface.

Summary:

In summary, the new Datex-Ohmeda S/5 Network and Central, described in this submission is substantially equivalent to the predicate device.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5 Network and Central '02 complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- EN60950: 1995 (IEC950 2nd edition) - Safety of information technology equipment, including electrical business equipment
- EN 55022: 1994 (IEC-CISPR 22) – Information technology equipment - Radio disturbance characteristics. Limits and methods of measurement
- EN 55024: 1998 – IT Equipment – Immunity characteristics
- EN 1441, Medical devices - Risk analysis
- EN 475, Medical devices - Electrically-generated alarm signals
- ISO 9703-1, ISO 9703-2, Anesthesia and respiratory care alarm signals
- IEC 60601-1-4
- CAN/CSA-C22.2 No 950: Information Technology Equipment Including Electrical Business Equipment
- UL1950: Information Technology Equipment Including Electrical Business Equipment
- ISO/IEC 8802-3 (ANSI/IEEE 802.3), EIA/TIA-568, EIA/TIA-TSB40, international network cabling standards
- ETS 300 826 (1997-11) – Radio Wideband Systems

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 Network and Central '02 as compared to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2002

Datex-Ohmeda
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Rd.
Needham, MA 02492

Re: K022507

Trade Name: Datex-Ohmeda S/5 Network and Central '02
Regulation Name: Network and Communication Physiological System
Regulation Number: 21 CFR 870.2300
Regulatory Class: Class II (two)
Product Code: MSX
Dated: July 27, 2002
Received: July 30, 2002

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 022507Device Name: Datex-Ohmeda S/5 Network and Central '02Indications For Use:

The Datex-Ohmeda S/5™ Network and Central transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several Centrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.

The Datex-Ohmeda S/5™ Central maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in Datex-Ohmeda monitor network. Network connections consist of hardwired network cables and/or Wireless LAN (WLAN) connections. Furthermore, it coordinates the transfer of information between devices in the Datex-Ohmeda S/5™ Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS).

The Datex-Ohmeda S/5™ Central can be used for remote monitor management, storing, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5™ ViewStation can be used for remote monitor management, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5™ Network will be used for patients in the hospital and it is meant for continuous use.

The device is for use by qualified personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Ashley Brown for BDZ (Optional Format 1-2-96)
(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K022507